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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,639	02/07/2001	Babak Nemati		7136
7	590 10/01/2002			
SUZANNAH K. SUNDBY, ESQ.			EXAMINER	
	OLMAN, PLLC I STREET, N.W.		HAYES, MICHAEL J	
WASHINGTO	N, DC 20004-2201	I	ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 10/01/2002	2

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)				
Office Action Summary		09/777,639	NEMATI, BABAK				
		Examiner	Art Unit				
		Michael J Hayes	3763				
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sh	eet with the correspondence ad	dress			
A SH THE - Exte after - If the - If NC - Failu - Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. In a period for reply specified above is less than thirty (30) days, a replayment or reply is specified above, the maximum statutory period ure to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailing date of the mailing patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however oly within the statutory minimu will apply and will expire SIX e, cause the application to be	may a reply be timely filed m of thirty (30) days will be considered timel (6) MONTHS from the mailing date of this c come ABANDONED (35 U.S.C. § 133).	y. ommunication.			
1)⊠	Responsive to communication(s) filed on 07	February 2001 .					
2a)[	This action is <b>FINAL</b> . 2b)⊠ T	his action is non-fina	l.				
3)	Since this application is in condition for allow closed in accordance with the practice under			ie merits is			
•	ion of Claims	.n					
4)[	Claim(s) <u>1-16</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra		nn				
5) 🗀		WIT HOIT CONSIGERATION	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
•	☑ Claim(s) is/are allowed.  ☑ Claim(s) <u>1-16</u> is/are rejected.						
7)							
<i>'</i> —	Claim(s) are subject to restriction and/	or election requireme	ent.				
• —	ion Papers		•				
9)[	The specification is objected to by the Examin-	er.	•				
10)⊠	The drawing(s) filed on 07 February 2001 is/ar	e: a)⊠ accepted or b	objected to by the Examiner.				
	Applicant may not request that any objection to the	he drawing(s) be held i	n abeyance. See 37 CFR 1.85(a).				
11)	The proposed drawing correction filed on	_ is: a)□ approved	b)	er.			
	If approved, corrected drawings are required in re	• •	1.				
12)	The oath or declaration is objected to by the E	xaminer.					
Priority	under 35 U.S.C. §§ 119 and 120						
•	Acknowledgment is made of a claim for foreig	n priority under 35 U	.S.C. § 119(a)-(d) or (f).				
a)	☐ All b)☐ Some * c)☐ None of:						
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
* (	3.☐ Copies of the certified copies of the price application from the International B See the attached detailed Office action for a lis	ureau (PCT Rule 17.	2(a)).	Stage			
14) 🔲 /	Acknowledgment is made of a claim for domes	tic priority under 35 l	J.S.C. § 119(e) (to a provisiona	l application).			
	a)  The translation of the foreign language pr Acknowledgment is made of a claim for domes						
Attachmer							
1) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 No	terview Summary (PTO-413) Paper No otice of Informal Patent Application (PT her:				

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 9, 10, 11, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by CHAN et al. (U. S. Patent No. 6,275,726 B1). Chan discloses a method of delivering a clarifying agent past a surface permeability layer of skin to covered biological tissue to enhance optical transparency.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 4-8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN as applied to claim 1 above, and further in view of EDWARDS (U. S. Patent No. 5,833,647). Chan discloses the claimed invention except for delivery by sonophoresis, electroporation, temperature gradient, iontophoresis. Edwards teaches the use of these methods to delivery drugs to a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Edwards in the method of Chan in order to effectively deliver a medicament transdermally.

Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN as applied to claim 1 above, and further in view of WEAVER et al. (U. S. Patent No. 5,019,034). Chan discloses the claimed invention except for using optical pressure and solvent to deliver the agent. Weaver teaches the use of optical pressure to drive molecules across skin barrier and penetrating solvents to increase skin permeability. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Weaver in the invention of Chan in order to effectively deliver fluids past the skin barrier.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN as applied to claim 1 above, and further in view of Henry et al. (J. Pharm. Sci. 87(8) pp 992-925. Chan discloses the claimed invention except for delivering the agent using needles to increase the skin permeability. Henry discloses using microneedles to increase skin permeability. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Henry in the invention of Chan in order to effectively deliver molecules across the skin barrier.

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## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh 26 September 2002

> MICHAEL J. HAYES PRIMARY EXAMINER

Michael / Hazer

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